

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JUDGE PAULEY

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VIVELLE VENTURES LLC (d/b/a NOVOGYNE)
PHARMACEUTICALS), NOVEN)
PHARMACEUTICALS, INC., and NOVARTIS)
PHARMACEUTICALS CORPORATION)
)

Plaintiffs,)

v.)

MYLAN TECHNOLOGIES, INC., MYLAN)
PHARMACEUTICALS, INC., and MYLAN, INC.)
)

Defendants.)
-----X

11 CV 1187

Civil Action No. _____



COMPLAINT

Plaintiffs, Vivelle Ventures LLC (d/b/a Novogyne Pharmaceuticals) ("Vivelle"),
Noven Pharmaceuticals, Inc. ("Noven") and Novartis Pharmaceuticals Corporation ("NPC")
(collectively, "Plaintiffs"), for their Complaint against defendants Mylan Technologies, Inc.
("MTI"), Mylan Pharmaceuticals, Inc. ("MPI"), and Mylan, Inc. (collectively, "Defendants"),
allege as follows:

Nature of the Action

1. This is an action for patent infringement arising under the patent laws of
the United States, Title 35, United States Code, Sections 100 *et seq.* This action relates to MTI's
Abbreviated New Drug Application ("ANDA") No. 201675 submitted to the United States Food
and Drug Administration (the "FDA") seeking approval to market a generic version of Plaintiffs'
Estradiol Transdermal System (Vivelle-Dot[®]), which is indicated in treatment of symptoms
associated with menopause, treatment of hypoestrogenism, and prevention of postmenopausal
osteoporosis.

The Parties

2. Vivelle is a joint venture between NPC and Noven, organized as a limited liability company under the laws of the State of Delaware, and having a place of business at 59 Route 10, East Hanover, NJ 07936.

3. Noven is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 11960 Southwest 144th Street, Miami, Florida 33186.

4. NPC is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at One Health Plaza, East Hanover, New Jersey 07936.

5. Upon information and belief, Defendant MTI is a corporation organized and existing under the laws of the State of West Virginia and has its principal place of business at 110 Lake Street, St. Albans, Vermont 92618.

6. Upon information and belief, MTI is a wholly owned subsidiary of Mylan, Inc.

7. Upon information and belief, MTI is engaged in the manufacture for sale of pharmaceutical products, including transdermal pharmaceutical products.

8. Upon information and belief, at Mylan, Inc.'s direction and control, MTI develops and manufactures products for sale and distribution by Defendant MPI in this judicial district and throughout the United States.

9. Upon information and belief, Defendant MPI is a corporation organized and existing under the laws of the State of West Virginia and has its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

10. Upon information and belief, MPI is a wholly owned subsidiary of Mylan, Inc.

11. Upon information and belief, MPI is engaged in the manufacture and sale of pharmaceutical products. Upon information and belief, MPI manufactures and/or distributes generic drugs for sale and use in this judicial district and throughout the United States at the direction, under the control, and for the benefit of Mylan, Inc.

12. Upon information and belief, Defendant Mylan, Inc. is a corporation organized and existing under the laws of the State of Pennsylvania and has its principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317, and has offices at 405 Lexington Avenue, New York, New York 10174, among other locations.

13. Upon information and belief, Mylan, Inc. established Defendant MPI and Defendant MTI for the purposes of manufacturing, distributing, marketing, and selling generic drug products in this judicial district and throughout the United States.

14. Upon information and belief, Mylan, Inc. controls and/or dominates MPI and MTI.

Jurisdiction And Venue

15. This Court has jurisdiction over the subject matter of this action pursuant to the provisions of 28 U.S.C. §§ 1331, 1338(a), 1400(b), 2201 and 2202.

16. MTI is subject to personal jurisdiction in this judicial district because it is licensed to do business in the State of New York and has designated an agent for service of process in this State and, on information and belief, it regularly and continuously transacts business within the State of New York, including, but not limited to, the regular sale of its products within the State of New York.

17. MPI is subject to personal jurisdiction in this judicial district because it is licensed to do business in the State of New York and has designated an agent for service of process in this State and, on information and belief, it regularly and continuously transacts business within the State of New York, including, but not limited to, the regular sale of pharmaceutical products within this judicial district.

18. Mylan, Inc. is subject to personal jurisdiction in this judicial district because, on information and belief, it regularly and continuously transacts business within the State of New York, including, but not limited to, causing through MTI and MPI the sale and distribution of pharmaceutical products within this judicial district and throughout the United States. Upon information and belief Mylan, Inc. maintains corporate offices at 405 Lexington Ave., New York, New York 10174.

19. Upon information and belief, MTI is the agent, affiliate, representative, and/or alter ego of, and/or acts in concert with MPI and Mylan, Inc. for the purposes of manufacturing, marketing, distributing, and selling generic pharmaceutical products within the United States, including the State of New York, and in seeking FDA approval to conduct such activities.

20. Upon information and belief, Defendants collaborate in the manufacture, marketing, and sale of many pharmaceutical products (including generic drug products manufactured and sold pursuant to approved ANDAs) within this judicial district and throughout the United States.

21. Upon information and belief, MTI acts as an agent of MPI and Mylan, Inc. with respect to the acts complained of herein.

22. Upon information and belief, the acts of MTI complained of herein were done at the direction of, with the authorization of, with the cooperation, participation, and assistance of and, in part, for the benefit of, MPI and Mylan, Inc.

23. Venue is proper in this judicial district pursuant to the provisions of 28 U.S.C. §§ 1391 and 1400(b).

The Patents-In-Suit

24. United States Letters Patent Nos. 5,656,286 entitled “Solubility Parameter Based Drug Delivery System and Method for Altering Drug Saturation Concentration” (the “’286 patent”), a copy of which is attached hereto as Exhibit A, was duly issued by the United States Patent and Trademark Office on August 12, 1997 to inventors Jesus Miranda and Steven Sablotsky.

25. Noven is the lawful owner of the ’286 patent by assignment of all right, title and interest in and to the ’286 patent.

26. United States Letters Patent Nos. 6,024,976 entitled “Solubility Parameter Based Drug Delivery System and Method for Altering Drug Saturation Concentration” (the “’976 patent”), a copy of which is attached hereto as Exhibit B, was duly issued by the United States Patent and Trademark Office on February 15, 2000 to inventors Jesus Miranda and Steven Sablotsky.

27. Noven is the lawful owner of the ’976 patent by assignment of all right, title and interest in and to the ’976 patent.

28. The ’286 and ’976 patents claim, *inter alia*, transdermal drug delivery systems comprising pressure-sensitive adhesive compositions, including transdermal drug

delivery systems comprising compositions designed to affect the rate of drug delivery. The claimed systems include transdermal drug delivery systems for estradiol.

29. NPC holds an exclusive license under the '286 and '976 patents from Noven for transdermal patch products containing estrogen as a single active ingredient.

30. Vivelle holds an exclusive sublicense from NPC under its rights in the '286 and '976 patents.

The Vivelle-Dot[®] Drug Product

31. NPC holds an approved New Drug Application (No. 20-538) for an estradiol transdermal system (continuous delivery for twice-weekly application), which is marketed and sold by Vivelle under the registered trademark Vivelle-Dot[®].

32. Pursuant to 21 U.S.C. § 355(b)(1) and attendant regulations, the '286 and '976 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") with respect to Vivelle-Dot[®].

Acts Giving Rise to this Action

33. By letter dated January 11, 2011, MTI notified Noven and NPC that it had filed ANDA No. 201675 with the FDA seeking approval to market Estradiol Transdermal System, USP (Twice-Weekly), 0.025 mg/day, 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day, and 0.1 mg/day ("Mylan's ANDA Product") prior to the expiration of the '286 and '976 patents. MTI's letter included a statement pursuant to 21 U.S.C. § 355(j)(2)(vii)(IV) of the "factual and legal bases" for MTI's opinion that the '286 and '976 patents are not valid, are unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Mylan's ANDA Product.

34. Upon information and belief, at Mylan, Inc.'s direction and control, Defendants collaborated in the research, development, preparation and filing of ANDA No. 201675 for Mylan's ANDA Product.

35. Upon information and belief, pursuant to Section 505(j) of the Federal Food Drug and Cosmetic Act (21 U.S.C. § 355(j)), MTI filed with the FDA ANDA No. 201675 seeking approval to engage in the commercial manufacture, use and sale of Mylan's ANDA Product. On information and belief, MTI stated to the FDA in its ANDA that Mylan's ANDA Product is qualitatively and quantitatively the same as Plaintiffs' approved Vivelle-Dot® product.

36. Upon information and belief, MTI's ANDA No. 201675 was submitted to obtain FDA approval to engage in the commercial manufacture, use and sale of Mylan's ANDA Product prior to the expiration of the '286 and '976 patents.

37. Upon information and belief, MTI's ANDA No. 201675 contained a "Paragraph IV" certification pursuant to 21 U.S.C. § 355(j)(2)(vii)(IV) stating that in MTI's opinion the '286 and '976 patents are invalid or unenforceable or would not be infringed by the manufacture, use or sale of Mylan's ANDA Product.

38. Upon information and belief, ANDA 201675 was filed for the benefit of all Defendants.

39. Upon information and belief, Defendants were aware of the '286 and '976 patents when ANDA 201675 was filed containing the Paragraph IV certification.

Count I: Infringement of the '286 Patent

40. MTI's filing of ANDA No. 201675 constitutes infringement of one or more of the claims of the '286 patent under 35 U.S.C. § 271(e)(2).

41. Upon information and belief, MPI and Mylan, Inc. have also infringed, induced or contributed to and will infringe, induce or contribute to infringement of one or more

claims of the '286 patent by acting in concert and actively aiding, abetting, encouraging, and inducing MTI to (1) file ANDA No. 201675 for Estradiol Transdermal System, USP (Twice-Weekly) and (2) manufacture Mylan's ANDA Product pursuant to that ANDA.

42. Upon information and belief, upon FDA approval, MPI will sell and distribute Mylan's ANDA Product which will result in direct infringement of one or more claims of the '286 patent.

43. MTI's ANDA and Defendants' intention to engage in the commercial manufacture, use, offer to sell or sale of Mylan's ANDA Product upon receiving FDA approval prior to expiration of the '286 patent creates an actual and justiciable controversy with respect to infringement of the '286 patent.

44. Upon FDA approval of MTI's ANDA, Defendants will infringe the '286 patent by making, using, offering to sell, and selling Mylan's ANDA Product in the United States, and by actively inducing and contributing to infringement by others, unless enjoined by this Court.

45. Plaintiffs will be substantially and irreparably damaged and harmed if Defendants' infringement of the '286 patent is not enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count II: Infringement of the '976 Patent

46. MTI's filing of ANDA No. 201675 constitutes infringement of one or more of the claims of the '976 patent under 35 U.S.C. § 271(e)(2).

47. Upon information and belief, MPI and Mylan, Inc. have also infringed, induced or contributed to and will infringe, induce or contribute to infringement of one or more claims of the '976 patent by acting in concert and actively aiding, abetting, encouraging, and

inducing MTI to (1) file ANDA No. 201675 for Estradiol Transdermal System, USP (Twice-Weekly) and (2) manufacture Mylan's ANDA Product pursuant to that ANDA.

48. Upon information and belief, upon FDA approval, MPI will sell and distribute Mylan's ANDA Product which will result in direct infringement of one or more claims of the '976 patent.

49. MTI's ANDA and Defendants' intention to engage in the commercial manufacture, use, offer to sell or sale of Mylan's ANDA Product upon receiving FDA approval prior to expiration of the '976 patent create an actual and justiciable controversy with respect to infringement of the '976 patent.

50. Upon FDA approval of MTI's ANDA, Defendants will infringe the '976 patent by making, using, offering to sell, and selling Mylan's ANDA Product in the United States, and by actively inducing and contributing to infringement by others, unless enjoined by this Court.

51. Plaintiffs will be substantially and irreparably damaged and harmed if Defendants' infringement of the '976 patent is not enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

A. A judgment declaring that Defendants have infringed, and that Defendants making, using, selling, offering to sell or importing Mylan's ANDA Product described in ANDA No. 201675 will constitute infringement, contributory infringement and actively inducing infringement of the '286 patent;

B. A judgment declaring that Defendants have infringed, and that Defendants making, using, selling, offering to sell or importing Mylan's ANDA Product described in ANDA

No. 201675 will constitute infringement, contributory infringement and actively inducing infringement of the '976 patent;

C. A judgment providing that the effective date of any FDA approval for Defendants to make, use, sell, offer for sale, or import Mylan's ANDA Product described in ANDA No. 201675 be no earlier than the date on which the '976 patent expires or any later expiration of exclusivity to which Plaintiffs are or become entitled;

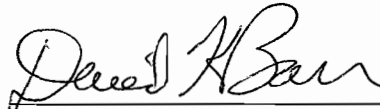
D. A judgment permanently enjoining Defendants, their officers, agents, servants, employees, parents, subsidiaries, affiliate corporations, other business entities and all other persons acting in concert, participation or privity with them, their successors and assigns, from infringing, contributorily infringing or inducing others to infringe the '286 and '976 patents;

E. If any Defendant engages in the commercial manufacture, use, offer to sell or sale of Mylan's ANDA Product prior to the expiration of the '976 patent, a judgment awarding plaintiffs damages resulting from such infringement, together with interest.

- F. Costs and expenses in this action; and
- G. Such further and other relief as this Court may deem just and proper.

Dated: New York, N.Y.
February 22, 2011

RESPECTFULLY SUBMITTED,

A handwritten signature in cursive script, appearing to read "David K. Barr", is written over a horizontal line.

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